

Notice of Allowability

Application No.

10/826,439

Examiner

Zachary C. Tucker

Applicant(s)

AN ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 September 2005.
2. ☒ The allowed claim(s) is/are 1-4 and 6-8.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Art Unit: 1624

Response to Amendment

As requested in the correspondence from applicants, filed 19 September 2006 (hereinafter "present amendment"), claims 1-4, 6 and 8 have been amended and the abstract has been replaced with the new abstract.

Election/Restrictions

Because the present amendment has overcome all previously set forth claim rejections, the subject matter of the elected Group, Group I is now in condition for allowance. Therefore, the Requirement for Restriction which was mailed to applicants on 28 March 2006 is hereby WITHDRAWN.

Claims 7 and 8, of Group III, are rejoined.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claim 4 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement of the above-captioned statute. The variable "W" in the molecular structure diagram of claim 4 as previously presented, for which no description is provided in the application, has been eliminated, and two new molecular structure diagrams are now in claim 4 – Formula 4 and Formula 5. These two structural formulae appear in the specification at page 8.

The rejection of claim 4 under 35 U.S.C. 112, first paragraph is hereby withdrawn.

In the previous Office action claims 1-4 and 6 were rejected under the second paragraph of the above-captioned statute, for indefiniteness. Specifically, the terms "substituted," in the absence of any group of substituents from which the substituent(s)

Art Unit: 1624

is/are to be selected, and “heterocycle” were deemed to render the claims indefinite in scope.

Because the specification does not provide any distinct, clear and concise definition of these terms, the claims, when read in light of the specification are not clearly defined.

In claim 4, it was noted that the variable “W,” which appeared in the molecular structure diagram represented in that claim did not have a corresponding definition associated with it. In claim 6, a variable “R,” which was *not* present in the molecular structure diagram represented in that claim, was defined, and the definition provided for that non-present “R” variable was confusing – specifying in the alternative that a COOH group could be bonded to “R” *via* “zero to three atoms” (what exactly constitutes being bonded *via* zero atoms was not clear).

In view of applicants’ present amendment, however, the claims are now clear and well-defined. Heterocycles have now been satisfactorily defined and the substituents contemplated for recitations of “substituted” are now set forth in the claims as well.

The variable “W” in claim 4 has been eliminated, in favor of structural formulae 4 and 5, which do not contain a “W” variable, and reference to a variable “R” in claim 6 has also been deleted.

The rejection of claims 1-4 and 6 as being indefinite under 35 U.S.C. 112, second paragraph, is hereby withdrawn.

Status of Claim Rejections - 35 USC § 102

In the previous Office action, claims 1 and 2 were rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication 2004/0006104 (Bush et al). By virtue of the present amendment, R₁ and R₂ are no longer permitted to be hydrogen

Art Unit: 1624

(H), so the compounds disclosed in Bush et al are no longer embraced by instant claims 1 and 2. The rejection of claims 1 and 2 as anticipated by Bush et al is hereby withdrawn.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 6,482,949 (Sessler et al). In view of the present amendment, which has eliminated from the definition of "X," the variable "R," the rejection is hereby withdrawn. "X" can therefore no longer be hydrogen. Sessler et al no longer discloses any compound embraced by the instant claims.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 6,518,423 (Kaneko et al). In view of the present amendment, which eliminates "R" from the definition of variable "X," the rejection is hereby withdrawn, because "X" can no longer be a hydrogen atom.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(b) as being anticipated US 6,103,720 (Lubisch et al). The present amendment to claim 2 eliminates "R" from the definition of variable "X," thereby eliminating hydrogen as a permitted identity for "X." The rejection based on Lubisch et al is therefore hereby withdrawn.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(b) as being anticipated by US 3,656,953 (Schlunke and Ronco). Upon review, the rejection appears to have been made in error. At most, compounds according to instant claim 2 may have been obvious in view of Schlunke and Ronco, as homologs of the compounds "J" and "V"

Art Unit: 1624

disclosed in Table 1 of that patent. The reference compounds in Schlunke and Ronco ("J" and "V") would have to have been ethyl esters, instead of methyl esters, to anticipate instant claim 2, wherein R_4 is H; Z is O; "X" is H and $()_{0-3}$ is zero. Even if compounds according to instant claim 2 were obvious prior to the present amendment, the present amendment would overcome such a rejection, because "X" is no longer permitted to be a hydrogen atom, as "R" is no longer a permitted identity for that variable.

The rejection based on Schlunke and Ronco is hereby withdrawn.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(b) as being anticipated by Silk, J.A. "Quinoxaline N-Oxides. V. Further bz-Substituted Derivatives" *Journal of the Chemical Society*, pages 2058-2063 (1956). The rejection based on the Silk reference is hereby withdrawn, because "X" is no longer permitted to be hydrogen, as "R" is not recited in the definition of that variable by virtue of the present amendment.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(b) as being anticipated by Gum and Joullié, "Structure vs. Reactivity in Quinoxalinecarboxylic Acids and Esters" *Journal of Organic Chemistry*, vol. 30(11), pages 33982-3985 (1965).

Like the previously noted prior art rejections (excluding the rejection based on Bush et al), the rejection of claim 2 based on Gum and Joullié is hereby withdrawn in view of the present amendment, which has eliminated from the definition of "X" the variable "R," so that hydrogen is no longer a permitted identity for "X."

In the previous Office action, claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Batulina et al, "N-Oxides of N-phenazinoyl Derivatives of Some α -Amino Acids" *Khimiko-Farmatsevticheskii Zhurnal*, vol. 4(11), pages 18-22 (1970), AS ABSTRACTED BY CAPLUS.

A full, Russian-language copy of the Batulina et al reference is submitted herewith, for applicants' review.

In view of the present amendment, which has deleted from the definition of R₃ the alternative of "alkyl," the rejection based on Batulina et al is hereby withdrawn.

In the previous Office action, claim 2 was rejected under 35 U.S.C. 102(b) as being anticipated by Spicer et al, "Dimeric Analogs of Non-Cationic Tricyclic Carboxamides are a New Class of Cytotoxic Agents" *Anti-Cancer Drug Design*, vol. 14(3), pages 281-289 (1999).

The rejection based on Spicer et al is hereby withdrawn, in view of the present amendment, which eliminates "R" as a permitted identity for the variable "X," thereby eliminating hydrogen as one of the permitted "X" definitions.

Allowable Subject Matter

Claims 1-4 and 6-8 are allowed.

The following is an examiner's statement of reasons for allowance:

All prior art-based rejections and rejections under 35 U.S.C. 112 have been overcome by applicants' amendment.

Art Unit: 1624

The closest prior art with respect to the instant claims are those references cited in the now-withdrawn prior art rejections, especially the Batulina et al reference, and the references cited of interest in the previous Office action at page 16.

A full copy of the Kora et al reference, cited on page 16 of the previous Office action, is submitted herewith for applicants' review.

One further reference, cited of interest, is:

Sueszer et al, "Preparation and Laboratory Evaluation of Cellulose-Based Ion Permselective Membranes" *Desalination*, vol. 7(1), pages 47-50 (1969). On page 48 of Sueszer et al, a compound similar to those according to instant claim 2, wherein Z is N, is disclosed. The authors employed this compound as a dye. Since "X" cannot be a hydrogen atom, the compound is not embraced by any of the instant claims.

The rejoined claims, claims 7 and 8, are drawn to a pharmaceutical composition comprising a compound according to any one of claims 1-4 and 6, and a method of treating hepatitis C infection, comprising administering a compound according to any one of claims 1-4 and 6. Both are supported and enabled by the disclosure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:
Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312;

Art Unit: 1624

information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.

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